K003120

DEC 1 8 2000

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 576-3544

Contact person: Kay A. Taylor

Date prepared: October 4, 2000

Predicate device

The Integra Reagent Cassette for Hemoglobin A1c on the COBAS Integra 400 is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Cobas® Integra Reagent Cassette for Hemoglobin A1c (K990992).

Device name

Proprietary name: Integra Reagent Cassette for Hemoglobin A1c

Common name: Hemoglobin A1c

Classification name: Glycolsylated Hemoglobin Assay

Device description

The device is an immunoturbidimetric test for the quantitative determination of Hemoglobin A1c in serum and plasma for use on the Integra family of analyzers.

510(k) Summary, continued

Intended use

An in vitro diagnostic reagent system intended for the quantitative determination of percent hemoglobin A1c in whole blood

Indication for use

Hemoglobin A1c results are useful for the monitoring of long-term blood glucose control in individuals with diabetes mellitus.

Substantial equivalence

The Integra Reagent Cassette for Hemoglobin A1c on the COBAS Integra 400 is substantially equivalent to other devices legally marketed for similar use in the United States. We claim equivalence to the Integra Reagent Cassette for Hemoglobin A1c on the COBAS Integra 700 (K990992).

Substantial equivalence-similarities

The Integra Reagent Cassette for Hemoglobin A1c on the COBAS Integra 400 is substantially equivalent to other devices legally marketed for similar use in the United States. We claim equivalence to the Integra Reagent Cassette for Hemoglobin A1c on the COBAS Integra 700 (K990992).

The following table compares the Integra Reagent Cassette for Hemoglobin A1c on the COBAS Integra 400 with the predicate device.

Feature	Hemoglobin A1c on Integra 400	Predicate Device (Integra 700)
Intended use	In vitro diagnostic reagent system intended for use on COBAS Integra 400 for the quantitative determination of percent hemoglobin A1c in whole blood.	In vitro diagnostic reagent system intended for use on COBAS Integra 400 for the quantitative determination of percent hemoglobin A1c in whole blood.
Indication for use	Useful for the monitoring of long-term blood glucose control in individuals with diabetes mellitus.	Useful for the monitoring of long-term blood glucose control in individuals with diabetes mellitus.
Methodology	Immunoturbidimetric	Immunoturbidimetric
Storage & Stability	On board in use at 8°C = 8 weeks	On board in use at 8°C = 8 weeks

Substantial equivalence – similarities, continued

Feature	Hemoglobin A1c on Integra 400	Predicate Device (Integra 700)
Specimen	• Venous blood (K_3-EDTA, Li-Heparin, Na-Citrate, K-Oxalate, Na-Fluroide) • Capillary blood	• Venous blood (K_3-EDTA) • Capillary blood
Wavelength	552 nm	552 nm
Measuring range	• 0.8 – 26 µmol/L, related to the 1:51 prediluted hemolysate. • 0.04 – 1.33 mmol /L test range for undiluted samples.	• 0.8 – 26 µmol/L, related to the 1:51 prediluted hemolysate. • 0.04 – 1.33 mmol /L test range for undiluted samples.
Calibration Interval	• Each lot • 57 days	• Each lot • 57 days

Substantial equivalence – differences

The following table illustrates the difference between the Integra Reagent Cassette for Hemoglobin A1c on the COBAS Integra 400 and the predicate device.

Feature	Hemoglobin A1c on Integra 400	Predicate Device (Integra 700)
Control	• sTfR Control Set	• HbA_1c Control N, HbA_1c Control P

Substantial equivalence – performance characteristics

The performance characteristics of the Integra Reagent Cassette for Hemoglobin A1c on the COBAS Integra 400 and the predicate device are equivalent.

Feature	Hemoglobin A1c on Integra 400	Predicate Device (Integra 700)
Within-run precision (%CV)	1.9% at 5% 1.6% at 12.1%	2.3% at 4.7% 2.2% at 10.3%
Total precision (%CV)	2.6% at 5% 2.9% at 12.1%	2.4% at 4.7% 2.4% at 10.3%
Lower Detection limit	0.8 µmol/L	0.8 µmol/L
Method Comparison - Passing-Bablok Correlation	Hgb A1c Integra 400 (Y) / Integra 700 (X) Y= 0.9575X + 0.379% r= 0.9964	Hgb A1c Integra 700 (Y) / Integra 700 hemolysate application (X) Y= 0.98X + 0.23% r= 0.997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kay A. Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
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P.O. Box 50457
Indianapolis, Indiana 46250-0457

DEC 18 2000

Re: K003120
Trade Name: Integra Reagent Cassette for Hemoglobin A1c
Regulatory Class: II
Product Code: LCP
Dated: October 4, 2000
Received: October 5, 2000

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A K003120

Device Name: Cobas® Integra Reagent Cassette for Hemoglobin A1c

Indications For Use:
An in vitro diagnostic reagent system intended for the quantitative determination of percent hemoglobin A1c in whole blood. Hemoglobin A1c results are useful for the monitoring of long-term blood glucose control in individuals with diabetes mellitus.

Prescription Use √ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003120